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IN THE

Supreme Court of the United States

October Term, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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Questions Presented

1. Whether a manufacturer of cyclandelate, a prescription drug sold in blue and blue/red capsules, can be granted a monopoly of the colors blue and blue/red for use on cyclandelate capsules.

This question arises because the Respondent, a brand name drug company which developed and patented cyclandelate, has obtained an injunction* against Petitioners' use of blue and blue/red on cyclandelate capsules, although the patent for cyclandelate has expired and the blue and blue/red colors are neither a trademark for Respondent's cyclandelate, nor patented.

2. Whether Petitioners, who are manufacturers and wholesalers of generic prescription drugs, are liable for "contributory trademark infringement" based solely on a finding that they could have anticipated that retail pharmacists would mislabel Petitioners' cyclandelate, or substitute Petitioners' cyclandelate for the Respondent's brand name cyclandelate.

This question arises because the Petitioners were found liable for "contributory trademark infringement" based solely on evidence that Petitioners sold cyclandelate in capsules that simulated the appearance of Respondent's brand name cyclandelate capsule and promoted their generic product as equivalent to the brand name product (which it was) and that 25 retail pharmacists mislabeled generic

* Respondent has also been awarded damages and Petitioners' profits resulting from Petitioners' sale of cyclandelate in blue and blue/red capsules.

cyclandelate as Respondent's brand name cyclandelate. Fifteen (15) of these pharmacists, who were known by Respondent to have a propensity for palming-off, substituted generic cyclandelate in filling prescriptions for the Respondent's brand name cyclandelate. This finding of "contributory trademark infringement" was made by the appellate court despite the trial court's findings that Petitioners had no knowledge of the mislabeling or palming-off, that the Petitioners properly labeled the generic cyclandelate they sold to retail pharmacists, that mislabeling and palming-off were not shown to be widespread, that the look-alike colors of the generic product were used by Petitioners because the colors were functional and that the Petitioners did nothing to encourage or suggest that retail pharmacists mislabel or palm-off the generic drug product.

3. Whether generic drug manufacturers and wholesalers should be enjoined from using the colors of the brand name drug product in manufacturing and marketing a generic equivalent, where the trial court found that the colors have therapeutic functions and are a significant factor in the commercial success of the product, and where the public policy of state law encourages the use of generic drug products in order to reduce the cost of health care for their citizens.

This question arises because the appellate court disregarded the trial court's factual findings, based on the testimony of doctors, pharmacists and businessmen in the drug industry, that the colors of the drug capsules were therapeutically functional, and an important ingredient of their commercial success. The appellate court did *not* rule that

the trial judge's findings of fact were clearly erroneous, but disregarded them as "unconvincing" because the evidence introduced by Petitioners was not "persuasive" to a majority of the appellate court. Thus an injunction has issued forbidding Petitioners from making or selling their lower cost generic cyclandelate in blue and blue/red capsules; which coloring is useful to patients and doctors, and important in marketing the product.

Parties to Proceeding Below

The parties to the proceeding in the United States Court of Appeals for the Second Circuit, whose judgment is sought to be reviewed, are Ives Laboratories, Inc. (Plaintiff-Appellant below, Respondent hereto) and Darby Drug Co., Inc., Inwood Laboratories Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc. and Sherry Pharmaceutical Co., Inc. (Defendants-Appellees below, Petitioners hereto).

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Opinions Below

There are five opinions below, four of which have been officially reported. They are:

(a) The opinion of the United States District Court for the Eastern District of New York, denying the Respondent's motion for a preliminary injunction, set forth in Appendix A.* 455 F. Supp. 939 (1978)

* The Appendix referred to herein has been submitted by petitioners Inwood Laboratories Incorporated and Premo Pharmaceutical Laboratories, Inc., together with their separate petition. Numbers in parentheses followed by the letter "a" are references to page numbers in the Appendix.

(b) The opinion of the Court of Appeals for the Second Circuit affirming the District Court's denial of Respondent's motion for a preliminary injunction, set forth in Appendix B. 601 F.2d 631 (1979)

(c) The opinion of the United States District Court for the Eastern District of New York dismissing the Respondent's complaint after trial, set forth in Appendix C. 488 F. Supp. 394 (1980)

(d) The opinion of the Court of Appeals for the Second Circuit reversing the District Court's dismissal of the Respondent's complaint and remanding the case to the District Court, set forth in Appendix D. 638 F. 2d 538 (1981)

(e) The memorandum opinion and order of the United States District Court for the Eastern District of New York dated May 12, 1981, issued pursuant to the mandate of the United States Court of Appeals for the Second Circuit (78 Civ. 372) are unreported. They are set forth in Appendix F.

Jurisdiction

The judgment of the United States Court of Appeals for the Second Circuit was entered on January 8, 1981, and an order of said court denying Petitioners' petition for rehearing was filed on February 25, 1981. On May 13, 1981, Justice Thurgood Marshal of the United States Supreme Court signed an order extending Petitioners' time to file this Petition for Writ of Certiorari to June 25, 1981.

The jurisdiction of the United States Supreme Court is invoked under the provisions of Title 28, United States Code, §1254(1).

Constitutional Provisions and Statutes Involved

United States Constitution:

Article I, Section 8, Clause 8

First Amendment

The statutes which this case involves are as follows:

The Lanham Trademark Act of 1946 (herein "The Lanham Act"):

§32, 15 U.S.C. §1114
§43(a), 15 U.S.C. §1125(a)

New York Education Law (McKinney's):

§6810
§6815 (2) (h) and (j)
§6816
§6816-a

New York Public Health Law (McKinney's):

§206 (1)(o)

These stautes are set forth in Appendix G.

Statement of the Case

a. Jurisdiction and Procedural Background

The federal courts have jurisdiction of this case pursuant to 28 U.S.C. §§1331 and 1338. (56a)

The Respondent, Ives Laboratories, Inc. ("Ives"), which makes and sells the prescription drug cyclandelate under the trademark Cyclospasmol brought this action seeking an injunction and related relief against Petitioners (sometimes referred to herein as defendants) who make and sell cyclandelate under its generic name, based upon claimed violations of §§32 and 43(a) of the Lanham Act (15 U.S.C. §§1114 and 1125(a)) and the New York State law of unfair competition. Ives sought a preliminary injunction which was denied by the district court (455 F. Supp. 939, Appendix A). The denial of a preliminary injunction was affirmed by the Court of Appeals for the Second Circuit (601 F.2d 631, Appendix B). The district court dismissed the complaint after trial (488 F. Supp. 394, Appendix C) and Ives appealed. The appellate court reversed the district court's dismissal of the complaint (638 F.2d 538, Appendix D) and remanded the case to the district court with a mandate to grant relief consistent with the opinion of the appellate court. On remand, the district court granted Ives an injunction, damages, defendants' profits and a recall of defendants' product. (Appendix F)

Petitioners seek review of the judgment of the Court of Appeals for the Second Circuit (Appendix D) which reversed the trial court's dismissal of Ives' complaint.

b. Factual Background

The drug cyclandelate, a white powder, is a peripheral vasodilator claimed to produce an increase in blood flow and thereby inhibit the progressive conditions caused by certain vascular diseases which tend to occur in the aged. Cyclandelate is therefore prescribed for a long period of time, generally for the rest of the patient's life. For some years, Ives, its predecessors and its parent company, American Home Products Corporation, have sold the drug under the mark Cyclospasmol and, until the patent on cyclandelate expired on April 26, 1972, had the exclusive right to make and sell the drug in the United States. Ives has been marketing 200 mg. dosages in a pale blue capsule imprinted "Ives 4124" since 1962, and 400 mg. dosages in red and blue capsules imprinted "Ives 4148" since 1975. (56a-57a)

Because the drug may be dispensed only on prescription, Ives has directed its promotion primarily to physicians. Some 230 salesmen called "detail" men have made personal visits to doctors and distributed samples and promotional materials. (57a)

Of the defendants, three are manufacturers: Premo Pharmaceutical Laboratories, Inc. ("Premo"), Inwood Laboratories, Incorporated ("Inwood"), and MD Pharmaceutical Company, Inc. ("MD"). All three purchase cyclandelate and empty capsules, and assemble the product for sale to wholesalers and hospitals. Inwood and MD also sell to retail pharmacies. Premo and Inwood sell 200 mg. and 400 mg. capsules in colors identical to those used by Ives. MD does the same with 200 mg. capsules. Defendants, Darby Drug Co., Inc., Rugby Laboratories, Inc., and Sherry

Pharmaceutical Co., Inc. (collectively "the wholesalers") purchase capsules of the kind made by the manufacturers and sell them primarily to physicians and pharmacies. (57a)

The defendants promote their generic product as comparable, similar or equivalent to Cyclospasmol in price lists and catalogs distributed to their customers.* Defendants do not utilize salesmen or "detail" men who visit their customers, as does Ives. Some of defendants' catalogs refer to the color of the capsules. Defendants' names appear on their packages of cyclandelate capsules. (57a, 58a)

The defendants' cyclandelate and Ives' Cyclospasmol are delivered to pharmacists in bottles containing the name of product and the name of the seller. Ives bottles identify its cyclandelate with the brand name Cyclospasmol. The bottles are opened by the pharmacists and the capsules transferred to smaller containers which bear the pharmacists' own label and are dispensed to consumers. (58a)

The New York Education Law defines a pharmacist's obligations in dispensing prescription drugs. The relevant provisions require a doctor's prescription form to state that it will be filled with a generic product unless the doctor prescribes by brand name and signs the form over the line stating "dispense as written". (Education Law §6810(6)) If the doctor signs over the other signature line on the prescription form, which reads "substitution permissible," the druggist must dispense a less expensive drug having the same active ingredients, provided that drug appears on a

* There was no proof at trial that defendants' cyclandelate had any different therapeutic effect than Ives' Cyclospasmol brand cyclandelate, and that was not an issue in the case.

list maintained by the State for such purpose. (Education Law §6816-a(1)) If the drug is not on the list, the druggist may, but is not required to, substitute the less expensive generic drug. (58a)

The label placed on the bottle by the druggist must contain the brand name of the drug, if it has one, or the generic name and the name of the manufacturer. (Education Law §6816(a)) Therefore, a druggist dispensing Ives' Cyclospasmol brand cyclandelate must put "Cyclospasmol" on the label. However, if cyclandelate as sold by the defendants is dispensed, the label must state the word "cyclandelate" and the name of the manufacturer (e.g., "cyclandelate Premo"). (58a)

Violation of the Education Law subjects a pharmacist to criminal law penalties and loss of his license. (Education Law §6816(1)(a)) (116a, 117a)

c. Capsule Colors Are Not an Ives Trademark.

Ives claimed that the defendants use of look-alike capsules constituted a false designation of origin in violation of Section 43(a) of the Lanham Act, 15 U.S.C., §1125(a). The trial court rejected this contention on two grounds. Firstly, the trial court found the colors to be functional and therefore not entitled to trademark protection. (63a) Secondly, the court noted that even if the colors were not functional, Ives failed to show that they acquired secondary meaning, i.e., Ives did not demonstrate that patients identified the capsule colors with the source of the medication. (64a) There being no showing that capsule colors designate origin, the use of look-alike capsules by the defendants did not constitute a false designation of origin under §43(a). This finding by the trial court was not discussed or reversed by the court of appeals. (Appendix D)

d. The Charge of Contributory Trademark Infringement

Ives claims that a significant number of pharmacists palm off defendants' cyclandelate capsules in filling prescriptions for Cyclospasmol, and use Ives' trademark "Cyclospasmol" on the labels of bottles containing generic cyclandelate. Ives also claims that a significant number of pharmacists mislabel generic cyclandelate as Cyclospasmol when filling prescriptions calling for generic cyclandelate. This misuse of Ives' trademark, Cyclospasmol, by pharmacists engaging in the practice of illegal substitution and mislabeling, constitutes a violation of §32 of the Lanham Act. (110a, 111a)

Ives makes no claim against the offending pharmacists, but charges that the defendants contribute to those forms of trademark infringement by selling cyclandelate in capsules that are blue and blue/red, similar in appearance to Cyclospasmol capsules, and by promoting the sale of generic cyclandelate in catalogs and price lists stating defendants' product to be equivalent to Cyclospasmol. Ives claims that these activities alone constitute contributory trademark infringement making the defendants violators of §32 of the Lanham Act. (76a) There was no evidence that any defendant suggested illegal substitution or mislabeling to any pharmacist. In fact, defendants have no salesmen or "detail" men who visit pharmacies and were not shown to have knowledge of, or reason to know of, any pharmacist engaging in illegal substitution or mislabeling. (59a)

The only other evidence presented by Ives to support its claim of contributory trademark infringement was (a) the results of a nationwide shopping investigation which

disclosed only fifteen instances of illegal substitution, and (b) the results of a New York State survey which showed that ten pharmacists out of 83 mislabeled the product by using the name Cyclospasmol on bottles containing generic cyclandelate. (59a-60a)

The fifteen instances of illegal substitution were obtained in an uncontrolled nationwide investigation conducted by Ives' employees and "detail" men. The "detail" men were instructed to submit prescriptions for Cyclospasmol to pharmacies which Ives knew had a propensity to palm off generic products for expensive brand name products. (60a)

The ten instances of mislabeling were obtained in a survey involving prescriptions for Cyclospasmol signed on the line stating "substitution permitted" which were submitted to 83 pharmacists. Ten pharmacies mislabeled the generic product by using the word Cyclospasmol on the label, however five of these also indicated on the label that a generic form of Cyclospasmol was being dispensed, by using the phrase "generic Cyclospasmol" or the like. Nine of the ten pharmacies which mislabeled, informed the purchaser that generic cyclandelate was being dispensed, and only one pharmacy appeared to have charged the higher Cyclospasmol price for the generic product. (60a)

Although it was conceded by most of the defendants that using look-alike capsules could facilitate illegal substitution of a generic product in filling a prescription calling for a brand name product by pharmacists having a desire to engage in such activity, there was no evidence to connect the use of look-alike capsules to the instances of substitution or mislabeling described above.

With respect to the question of whether illegal substitution of generic products for brand name products was a widespread practice, the President of the New York State Pharmaceutical Society, called as a witness by Ives, testified that he did not believe the practice to be widespread (638 F.2d 538 at p. 545). (85a)*

The testimony of three doctors and two pharmacists called as witnesses for the defense showed that the color of drug capsules used in connection with long-term, maintenance medication relieves patient anxiety by assuring the patient that he is receiving the same medication he has previously received, avoids confusion among patients who take various types of medication in a single day, aids communication between doctors and patients in discussing the effects of medication and instructions for its use, and aids in identifying medication consumed by patients in emergency situations. Several witnesses, including one of the pharmacists referred to above and a businessman employed by a generic drug company, testified to the difficulty in marketing generic products which differed in appearance from the brand name product containing the same active ingredient. Such generic products which differ in appearance from the related brand name product are not readily accepted in the marketplace. The trial court made a factual finding that the colors of the drug product were functional, based upon the testimony described above (488 F. Supp. 394 at 398-399). (63a)

The evidence presented by defendants that capsule colors are functional is related to Ives' charge of contributory trademark infringement under §32 of the Lanham

* Mr. Lawler was Ives' witness. The error in the printed opinion has been corrected.

Act (15 U.S.C. 1125) because such evidence disputes Ives' claim that the use of look-alike capsules was undertaken by the defendants for the purpose of suggesting illegal substitution and mislabeling to pharmacists.

e. Judicial Standard of Contributory Trademark Infringement

In his opinion affirming the initial decision of the District Court (which denied Ives' motion for a preliminary injunction, 455 F. Supp. 939), Judge Friendly writing for the Second Circuit attempted to establish guidelines for determining liability under the doctrine of contributory trademark infringement. (34a, 35a)

The trial judge had defined contributory trademark infringement as "the knowing and deliberate instigation of such a practice" (455 F. Supp. at 945). Judge Friendly found that definition too narrow, and defined the doctrine for the edification of the trial court as follows:

> ". . . a manufacturer or wholesaler would be liable under §32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described. The proper criteria are stated in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F. Supp. 980, 989 (D. Mass. 1946) (Wyzanski, J.), affd., 162 F.2d 280 (1 Cir.), cert. denied, 332 U.S. 809 (1947)." 601 F.2d at 636 (35a)

After trial, the District Court considered whether the defendants' acts of selling look-alike generic cyclandelate

capsules and promoting them in catalogs as equivalent to Ives' Cyclospasmol brand cyclandelate, taken together with the proof of mislabeling and illegal substitution described above, constituted contributory trademark infringement. Using Judge Friendly's definition, the trial court found that:

> ". . . defendants did not suggest, even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply trademark Cyclospasmol. Nor did Ives show that defendants continued to sell the generic drug to pharmacists who defendants knew or had reason to know were engaging in such a practice. 601 F.2d at 636." 488 F. Supp. at 397 (59a)

On appeal after trial, Judge Mansfield, writing for a majority of the Second Circuit, reversed this finding of the trial court and found defendants liable for contributory trademark infringement. In doing so, the court revised and expanded the doctrine of contributory trademark infringement set down by Judge Friendly, finding the defendants liable because they:

> "could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage. This amounted to a suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct." 638 F.2d at 543 (82a, 83a)

In order to find the defendants liable for contributory trademark infringement, even under its expanded standard, the majority disregarded the trial court's factual finding

that the capsule colors were functional. Without holding that finding to be "clearly erroneous", Judge Mansfield dismissed it as "unconvincing". 638 F.2d at 544. (84a, 85a) By thus disregarding the defendants' reasons for using look-alike capsules, the Second Circuit supported its opinion that the defendants did so only to suggest that pharmacists mislabel the generic drug product.*

On remand, Judge Nickerson decided that the majority opinion of the Court of Appeals required him to grant a permanent injunction giving Ives a monopoly over the colors blue and blue/red for capsules containing cyclandelate. Judge Nickerson also awarded Ives a recall of defendants' product, damages and defendants' profits. (98a)

Reasons for Granting the Petition

Certiorari should be granted in order to determine:

1. The extent to which federal courts may grant a monopoly to products which are neither protected by patent or trademark under the Lanham Act.

2. The limits of the doctrine of contributory infringement under the Lanham Act.

3. The extent to which the public policy of States to encourage the use of lower priced generic drugs requires generic drug manufacturers be allowed to make drugs which look like brand name drugs.

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* The majority also reinforced its holding that the defendants could reasonably anticipate mislabeling by pharmacists, by considering evidence of unproved indictments then pending in the New York State criminal courts. 638 F.2d at 544 (84a)

I. The Creation of a Monopoly

Defendants have been enjoined from making and selling capsules of generic cyclandelate in the same color as Ives' Cyclospasmol. Ives' coloring was not trademarked (indeed would not qualify for trademark) and did not attain secondary meaning.

Nevertheless, the Second Circuit enjoined the defendants' use of blue and blue/red cyclandelate capsules, ruling:

> "By using capsules of identical color, size and shape, together with a catalog describing their appearance and listing comparative prices of Cyclospasmol and generic cyclandelate, appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademarked CYCLOSPASMOL or that bottles of their lower priced product might be mislabeled as Cyclospasmol, all to the druggists' economic advantage. This amounted to a suggestion, at least by implication, that the druggist take advantage of the opportunity to engage in such misconduct. By using look-alike capsules appellees also reduced the likelihood that patients who were given a generic substitute would bring that fact to their doctor's, (or their druggist's) attention. Similar activity has been enjoined as enabling druggists to defrand by palming off .... We think appellees' activity should be enjoined as well." 638 F.2d at 543 (82a, 83a)

While the court was justifiably concerned about protecting consumers from those few pharmacists who charge the brand name price and dispense the generic drug, the effect

of the court's decision grants the brand name company a monopoly over a functional aspect of the product. This will inure only to the economic advantage of Ives, whose patent monopoly is, in effect, extended indefinitely. The public at large suffers because they must pay the brand name price in order to buy cyclandelate in familiar blue and blue/red capsules.

Thus this case raises the issue of the extent to which a a monopoly of an unpatented aspect of a product (i.e., color), with no trademark status, may be created by the courts under the Lanham Act and the doctrine of contributory trademark infringement.

This Court has ruled that the states may not create common law monopolies in unpatented articles. See *Sears Roebuck & Co.* v. *Stiffel*, 376 U.S. 225, 11 L.Ed. 2d 661, 84 S.Ct. 784 (1964); *Compco* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234, 11 L.Ed. 2d 669, 84 S.Ct. 779 (1964), *reh. den.* 377 U.S. 913, 12 L.Ed. 183, 84 S.Ct. 1162 (1965). And in *William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526, 44 S.Ct. 615, 68 L.Ed. 1161 (1924) the Court ruled that although there was evidence of salesmen improperly suggesting the substitution of defendant's product for plaintiff's more costly product, there could be no injunction against the defendant using the same coloring as plaintiff's product.

The Attorney General of the United States in an amicus brief before the Second Circuit on the first appeal (Appendix B), aptly described the importance of this case when he stated:

"Appellant herein seeks to obtain an exclusive right to use a drug capsule color for marketing its previously patented drug cyclandelate. Such a right would seriously undercut the policies articulated by the Supreme Court in *Sears Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964), and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), by conferring exclusive rights in an item not qualifying for a monopoly grant under federal patent standards.

"The issue of freedom to compete by copying unpatented articles is especially important in the prescription drug field. Markets for particular prescription drug products are often dominated by major 'brand name' drug companies that have gained their dominant positions through exclusive marketing of the products under patents. *See, e.g., Smith Kline Corp.* v. *Eli Lilly & Co.*, 575 F.2d 1056, 1059-1061, 1065 (3rd Cir. 1978). Once a patent expires, the patent laws envision free and open competition in the product. When the competitive market conditions contemplated by the patent laws for the post-expiration period fail to materialize, society incurs a cost; as a result of successful brand differentiation the established firm often maintains a dominant market share even though its competitors offer the same product at a substantially lower price.

"Colored capsules are an important marketing tool in the post-patent expiration period. As a result of the exclusive sale of a patented drug in a particular colored capsule during the lengthy patent period, customers may identify the colored capsule with the therapeutic action of the product. A prohibition of copying the colors of such capsules would tend to perpetuate the market power conferred by the expired patent and create an artificial and unnecessary barrier to entry and successful competition in the sale of the particular drugs.

> "Patents on numerous important prescription drugs have recently expired or will expire in the next years. J. H. Goldberg, 'MAC's Impact: What's Really Ahead for the Drug Field?' Drug Topics, Dec. 1, 1975. The decision in this case will therefore have a significant impact on the state of competition and prices in the prescription drug field. The United States seeks to assure that no artificial barriers to competition are constructed and that the public obtains the intended benefits of free competition in the post-patent expiration period." (Pages 2 & 3 of amicus brief, footnotes omitted).

The Second Circuit's split decision reversing the trial court has given to Ives a monopoly on color notwithstanding the trial court's factual finding that the capsule color was functional, notwithstanding the legion of cases which hold that a color cannot be trademarked or copyrighted (see *Norwich Pharmacal Co.* v. *Sterling Drug Inc.*, 271 F.2d 569 at 572 [2 Cir. 1959] *cert. denied* 362 U.S. 919 [1960]), notwithstanding the trial court's finding (undisputed by the Mansfield majority) that the capsule colors used by Ives did not identify Ives and had not acquired secondary meaning, notwithstanding that the use of the same color did not cause confusion on the consumer level (patients do not pick their drugs by brand name or otherwise off the shelf) or the pharmacist level, notwithstanding that the actual infringement complained of on the pharmacist level constitutes a criminal offense, and notwithstanding the testimony of Ives' own witness that illegal substitution is not widespread.

This Court should review the granting of such a monopoly which sharply undercuts the policy underlying prior decisions of this Court favoring open competition of unpatented products. *Sears Roebuck & Co.* v. *Stiffel Co.*, *supra*, and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, *supra*.

II. The Issue of Contributory Infringement

While it has long been recognized that a party may be liable to the owner of a trademark if that party contributes in some manner to an infringement of that trademark by a third person, the limits and boundaries of this doctrine have never been ruled upon by the Supreme Court.

Until the opinion of the Second Circuit from which Petitioners seek to appeal, the accepted limits of the doctrine of contributory infringement had been established in *Coca Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F. Supp. 980, 989 (D.Mass. 1946) *aff'd* 162 F.2d 280 (1st Cir.) *cert. den.* 332 U.S. 809, 68 S.Ct. 110, 92 L.Ed. 386 (1947). In that case, Judge Wyzanski stated:

> "Before he can himself be held as a wrong-doer or contributory infringer one who supplies another with the instruments by which that other commits a tort, must be shown to have knowledge that the other will or can reasonably be expected to commit a tort with the supplied instrument. . . . The test is whether wrongdoing by the purchaser 'might well have been anticipated by the defendant.' *Reid, Murdoch & Co.* v. *H. P. Coffee Co.*, 8th Cir., 48 F.2d 817, 819, last two lines."

Indeed, in the first appeal to the Second Circuit Judge Friendly, following the *Coca Cola Company* case, *supra*, stated:

> "The authorities later reviewed indicate to us that a manufacturer or wholesaler would be liable under Sec. 32 if he suggested, even if only by implication, that a retailer fill his bottle with the generic capsule and apply Ives' mark to the label, or continue to sell capsules containing the generic drug which facilitated this

> to a druggist whom he knew or had reason to know was engaging in the practices just described." 601 F.2d 631, 636 (35a)

Clearly in both the *Coca Cola* case and in Judge Friendly's opinion knowledge or reason to believe that a particular customer of a particular defendant was placing the plaintiff's trademark on the defendant's product would be required to be shown before that defendant could be held liable as a contributory infringer. No such knowledge was shown at trial, nor is it attributed to the defendants in Judge Mansfield's majority opinion. Judge Mansfield does, however, make a finding that the defendants suggested mislabeling and illegal substitution. In doing so, on this record, he significantly extends the former limits of the doctrine of contributory infringement. Judge Mansfield states:

> "By using capsules of identical color, size and shape, together with a catalog describing their appearance and listing comparative prices of Cyclospasmol and generic Cyclandelate, appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademark Cyclospasmol or that bottles of their lower priced product might be mislabeled as Cyclospasmol, all to the druggist's economic advantage. This amounted to a suggestion, at least by implication, that the druggist take advantage of the opportunity to engage in such misconduct." 638 F.2d at 543 (82a, 83a)

The court thus ruled that reasonable anticipation that a druggist will mislabel "amounted to a suggestion" by defendants to druggists that they should mislabel. Defendants submit that such a ruling is an illogical and

dangerous extension of the doctrine of contributory infringement.

Moreover, the actions which the Second Circuit found to be suggestive to druggists were, until that decision, always thought to be nothing more than good competition—the making of an unpatented item using functional aspects of the competitor's product, and informing customers that the product was the same as the competitor's but lower priced. See *Sears Roebuck & Co.* v. *Stiffel*, 376 U.S. 225, 11 L.Ed. 2d 661, 84 S.Ct. 784 (1964); *Compco* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234, 11 L.Ed. 2d 669, 84 S.Ct. 779 (1964) *reh. den.* 377 U.S. 913, 12 L.Ed. 183, 84 S.Ct. 1162 (1965).

The result of the Second Circuit decision was, in the words of Judge Nickerson on remand: "to grant a permanent injunction giving plaintiff a monopoly over the colors blue and a combination of blue and red for capsules of the same shape and size as those used by plaintiff to sell Cyclospasmol." (98a)

It will be noted that the Second Circuit found the defendants to have violated solely Section 32 of the Lanham Act (15 U.S.C. Sec. 1114), which section only prohibits the use of another's trademark. Thus the defendants have been found to be contributory infringers only with respect to those druggists who placed generic cyclandelate in a bottle and used a label on that bottle containing Ives' trademark Cyclospasmol. Considering that there was no evidence of any direct suggestion or encouragement by the defendants for a druggist to mislabel the generic compound

with the Ives' trademark, the Second Circuit, by requiring an injunction against the defendants prohibiting them from using Ives' colors, went far beyond anything previously sanctioned by this Court. In *William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526, 44 S.Ct. 615, 68 L.Ed. 1161 (1924) the Court found that the Warner salesmen had suggested substituting Eli Lilly's product with Warner's. Despite such evidence, the Court reversed the injunction granted by the Court of Appeals prohibiting Warner from using chocolate in its coloring, which was the same coloring as Lilly's, and held that Lilly was entitled only to an injunction prohibiting such tactics by salesmen, a requirement that the Warner label be distinctive from Lilly's and that the label state "affirmatively that the preparation is not to be sold or dispensed as Coco-Quinine (Lilly's product) or to be used in filling prescriptions or orders calling for the latter." 265 U.S. 532-33, 44 S.Ct. at 618. Nevertheless, the Second Circuit, on a far less compelling record than the Supreme Court had before it in the *Warner* case, has held that because some druggists improperly labeled the generic compound with Ives' trademark, the defendants must be enjoined from making cyclandelate capsules in the same color as Ives'.

Ives' proof of contributory infringement was undeniably flimsy: a nationwide shopping investigation, conducted by Ives employees with no attempt at fairness, involving only druggists Ives knew had a propensity for illegal substitution, uncovered merely 15 instances of that practice; a survey of 83 pharmacies in New York State disclosed only ten instances of mislabeling and only one instance of overcharging a consumer; and no direct evidence of defendants suggesting, or knowledge of, illegal substitution or mis-

labeling. On this record the Second Circuit fashioned an extraordinary remedy, granting Ives the exclusive right to use certain colors in connection with an unpatented product —although the colors had no trademark status and were found to be functional by the trial court, and despite the availability of other remedies such as criminal sanctions against the offending druggists (New York Education Law, 6816[1][a]) or labeling requirements such as those imposed by this Court in the *Warner* case, *supra*. These limited remedies would not impede competition or prevent patients from obtaining the product in familiar and useful colors at the lower generic price. Instead the Second Circuit did that which courts have done only with the greatest reluctance and in the most compelling cases, it granted Ives a monopoly over colors used in connection with a product which all drug manufacturers and wholesalers are free to sell.

It is submitted that this mischievous result was achieved by the Second Circuit majority's expansion and misuse of the doctrine of contributory trademark infringement. Thus this case raises important questions as to the limits of that doctrine and the relief available in the event that a party is held to have been a contributory infringer.

III. The Court Decision in this Case Undercuts State Public Policy

The State of New York, like many other States, has passed laws encouraging the use of lower cost generic drugs as a method of helping to keep medical costs down. New York Education Law, Section 6810(6) provides that a prescription will be filled generically unless the physician

states to "dispense as written". Section 6816-a New York Education Law requires substitution of a "less expensive drug product" if the doctor allows substitution and the product is on a list established by Section 206 of the Public Health Law. The importance of containing medical costs is thus recognized in New York as being an important public policy consideration.

The District Court found that the color, size and shape of the capsules manufactured by the defendants were functional in that these capsules, by looking the same as Ives', reduced patient's confusion or anxiety in taking their medication, enabled doctors to communicate with the patients more easily concerning their medication, and aided in the identification of the drug in an emergency situation. (63a, 64a) While the Second Circuit found this analysis "unconvincing" it did not reverse the finding of facts by the District Court on this issue of functionality. (84a, 85a)

State public policy is to encourage competition between name-brand drugs and lower cost generic drugs. Obviously having the same color and shape as the name-brand drug will allow generic companies to more effectively compete with the brand-name product. It is ironic that the majority opinion below has used the Lanham Act, enacted to protect the consuming public, to instead grant monopolistic power over a functional aspect of an unpatented product, which will increase the cost of medication to those who can least afford it—the ill and the elderly.

Because of the important State policy of controlling costs through encouraging competition from generic drug manufacturers involved in this case, the Court should grant

the petition for certiorari and review the Second Circuit's opinion which has the effect of limiting and discouraging competition between generic and brand name drug companies by granting brand name companies a monopoly over an aspect of the product which is not entitled to trademark protection, i.e. color.

Conclusion

For the above reasons, it is respectfully submitted that a Writ of Certiorari should be issued to review the judgment of the United States Court of Appeals for the Second Circuit.

Respectfully submitted,

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